KENDALL LAW PC
Jamie L. Kendall (NJ ID No. 016492004)
Brad M. Welsh (NJ ID No. 076132013)
Alexandra H. Schulz (NJ ID No. 157612015)
308 E. Lancaster Avenue, Suite 315
Wynnewood, Pennsylvania 19096
jkendall@tkfirm.com
bwelsh@tkfirm.com
aschulz@tkfirm.com
Facsimile: 1.484.841.2067
Telephone: 1.484.414.4093

MORGAN LEWIS & BOCKIUS LLP
(A Pennsylvania Limited Liability Partnership)
Brian W. Shaffer (NJ ID No. 025651996)
1701 Market Street
Philadelphia, Pennsylvania 19103-2921
brian.shaffer@morganlewis.com
Facsimile: 1.215.963.5001
Telephone: 1.215.963.5000
Attorneys for Defendants
Guerbet LLC and Liebel-Flarsheim Company, LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KIMBERLY GREMO
Plaintiff,
v.
BAYER CORPORATION, ET. AL.,
Defendants.

NO. 1:19-CV-13432-NLH-AMD

MOTION RETURN DATE:
October 21, 2019

DEFENDANTS GUERBET LLC AND LIEBEL-FLARSHEIM COMPANY, LLC'S REPLY IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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Counsel for defendants Guerbet LLC ("Guerbet") and Liebel-Flarsheim Company, LLC ("L-F") (collectively, the "Guerbet Defendants") submit this Reply in support of the Guerbet Defendants' motion to dismiss Plaintiff's First Amended Complaint (the "Motion"). *See* Dkt. 77-1.

I. INTRODUCTION

Plaintiff's First Amended Complaint (the "FAC") is an assemblage of speculation and legal conclusions, lacking specific factual allegations that if proven true, would demonstrate the Guerbet Defendants' product can cause any physical injury when used at clinical doses in patients with healthy kidneys. As to all claims, Plaintiff's bald "defendant harmed me" allegations fail to establish a plausible claim for relief. The FAC fails to meet basic notice pleading standards because it does not distinguish which of the three chemically-distinct products or eleven defendants allegedly caused Plaintiff's injuries. The FAC also fails to sufficiently allege how *any* defendant's product was the proximate cause of her injuries—or how *any* gadolinium-based contrast agent ("GBCA") is even capable of causing the injury she allegedly suffered. The Opposition cures none of these deficiencies.

With respect to Plaintiff's individual claims, the Opposition does not meaningfully oppose the substantive arguments raised by the Guerbet Defendants. The Opposition does not contest that Plaintiff's New Jersey Products Liability ("NJPLA") claims – Counts I ("Failure to Warn") and II ("Design Defect") – lack sufficient allegations to establish that the Guerbet Defendants' GBCA product is the proximate cause of her purported injuries, or the type of physical injury that she has even suffered. Nor does the Opposition meaningfully challenge the preemption arguments as to either Count I or II. For Plaintiff's express warranty claim, the Opposition does not remedy the FAC's failure to describe any express statement made by the Guerbet Defendants to Plaintiff. Finally, the only punitive damages claim available to Plaintiff is preempted by New Jersey law, and Plaintiff's

Opposition does not establish any exception to this established principle.

II. ARGUMENT

A. PLAINTIFF DOES NOT ALLEGE SUFFICIENT FACTS TO STATE A PLAUSIBLE CLAIM FOR RELIEF AS TO THE GUERBET DEFENDANTS.

1. Plaintiff Fails the Notice Pleading Standard of Federal Rule 8.

Plaintiff's Opposition does not cure the FAC's failure to meet the notice pleading standard of Federal Rule of Civil Procedure 8(a)(2). The Opposition concedes that "simply nam[ing] all defendants without describing what any particular defendant actually did, or how those alleged activities might be actionable under the law" is a fatal deficiency. Opp. at 5. Plaintiff unpersuasively contends that she can sue every party connected to a GBCA by declaring that she received a GBCA manufactured by all of the defendants, that she retained some unidentified amount of gadolinium in her body, that she suffered "NSF-like" symptoms at a later point in time, and that these generic allegations are enough to sue all manufacturers of the GBCAs she received. *See id.* The Opposition and the FAC fails to explain which defendant's product harmed her, how she was injured, and the specific risk of injury that was missing from the Guerbet Defendant's warnings. The FAC fails for this reason and should be dismissed. *See* Motion 3-5.

Plaintiff does not contest that when a complaint indiscriminately lumps the conduct of defendants together, it fails to comply with Rule 8. *See Galicki v. New Jersey*, No. 14-169, 2015 WL 3970297, at *2 (D. N.J. June 29, 2015). Group pleading is deficient here because "Plaintiff names eleven defendants in this action and alleges to have been administered three chemically-distinct GBCAs over a nine-year period, yet she casts all of her allegations broadly against *all 'Defendants' and products.'*" Motion at 5 (emphasis added). Because the FAC fails to adequately link

the conduct of any defendant to her alleged injuries, it does not comply with Rule 8(a)(2)'s notice requirement and should be dismissed.

2. Plaintiff Fails to Allege Sufficient Facts to Establish a Plausible Claim for Relief as to the Guerbet Defendants.

The Opposition confirms that the only purported link between OptiMARK and Plaintiff's alleged injuries are Plaintiff's conclusory allegations and say-so. Opp. at 5-6. The Opposition points to paragraphs 111-150 and 165-167 as plausibly alleging that OptiMARK proximately caused specific injury to Plaintiff. Yet, these excerpts attempt to conflate Plaintiff's supposed injuries with NSF (a disease process that only occurs in people with impaired kidney function, which she does not allege she has). *See, e.g.*, FAC ¶¶ 111-123 (discussing only NSF in patients with impaired renal function). The Opposition frankly admits that this bait-and-switch tactic is the foundation of her case: Plaintiff asserts that she has plead a "causal connection ***between GBCAS and NSF***." Opp. at 5-6 (emphasis added). But whether GBCAs are capable of causing NSF is not the issue at hand, because Plaintiff does not allege impaired renal function. She is not among the class of patients in whom NSF – a medically-defined disease process – can occur.

Nor do the Opposition's cited excerpts explain how retention of gadolinium from clinical doses of GBCAs can cause any injury. *See, e.g.*, FAC ¶¶ 125-150 (discussing studies that document the phenomena of gadolinium retention but failing to identify even a single study observing any injury related thereto). None of the studies contained in paragraph 156 – which Plaintiff labels as "newly acquired evidence" – suggest that clinical doses of GBCAs cause any injury in patients with normal renal function. *See* FAC at ¶ 156 (referencing animal studies and anecdotal case reports from individuals without any explanation or commentary as to how

these studies can be extrapolated to find *any* risk of *any* injury in humans with normal kidney function at clinical GBCA doses).[1]

Lastly, the Opposition tries to avoid, and does not defend, the FAC's mischaracterization of the September 2017 FDA MIDAC discussions. Opp. at 6; Motion at 8. Plaintiff argues that she "and gadolinium injury plaintiffs in other cases" believe that a continuum of "gadolinium-induced injuries" exists. *Id.* Regardless of Plaintiff's belief, it is factually inaccurate to contend that the FDA MIDAC found there may be a continuum of injuries related to clinical use of GBCAs. *See Davis v. McKesson Corp., et al.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *11-12 (D. Ariz. Aug. 2, 2019) ("[t]he continuum Dr. Desche mentions is from gadolinium retention to gadolinium toxicity causing NSF. He does not say there is a continuum that includes a wide range of milder symptoms that encompasses [Gadolinium Toxicity] " and "[Dr. Williams] is talking about the universe of patients with renal impairment, not individuals like Plaintiff who have no renal impairment. Even then, the most he says is that there 'might' be a continuum and it is a 'reasonable idea.' He does not endorse [the plaintiffs'] continuum conclusion.").[2]

In sum, Plaintiff fails to plead factual allegations that, if true, plausibly allege that GBCAs cause the supposed medical condition "gadolinium toxicity," "GDD," or *any* of the symptoms she allegedly suffers from. Plaintiff has pleaded

[1] Plaintiff concedes that gadolinium retention is neither the injury she complains of nor a cognizable injury under New Jersey law. *See* Opp. at 7. Notably, of the twenty-nine subparts to paragraph 156, ten solely relate to gadolinium retention; while others relate to routes of administration not at issue in this present case (e.g., in-utero, intrathecal, epidural, etc.) and still others relate to anecdotal evidence. Her reliance on paragraph 156 in support of proximate cause illuminates that Plaintiff is trying to equate gadolinium retention with injury.

[2] Similarly, Plaintiff continues to misconstrue the actions of the U.S. FDA, European Medicines Agency ("EMA"), and other regulators as substantiating her claim that GBCAs can cause injury to patients with normal renal function. *See* Dkt 85 at 8-10. Yet, each of these agencies reached *an opposition* conclusion – that the existing medical and scientific evidence do *not* establish a causal link between GBCAs and *any* illness in renally-healthy patients. Motion at 7.

quintessential "the defendant-unlawfully-harmed-me accusation[s]," which do not meet the federal pleading standards and therefore require dismissal. *Iqbal*, 556 U.S. at 678, 689.

B. PLAINTIFF DOES NOT SUFFICIENTLY STATE CLAIMS UNDER THE NJPLA.

1. Plaintiff Fails to Plead Any Cognizable Injury.

Plaintiff concedes that actual physical harm is required to bring an NJPLA claim. Opp. at 7. Plaintiff further admits that "gadolinium retention alone" (i.e., gadolinium retention without resultant injury) is "not a compensable injury under the NJPLA." *Id.* Additionally, Plaintiff admits that "she is not seeking to pursue claims over gadolinium retention alone." *Id.* Moreover, Plaintiff does not dispute that to the extent that the FAC relies on gadolinium retention as a basis for recovery, it must be dismissed. Motion at 9-10.

In light of these concessions, the Opposition argues that Plaintiff has set forth a cognizable injury – gadolinium toxicity or "GDD." Opp. at 7. But for the reasons outlined above and in the Motion, the FAC does not plausibly allege that the Guerbet Defendants' GBCA product *can* cause either of these supposed medical conditions, or the specific physical injury proximately caused by administration of the Guerbet Defendants' GBCA product. *See supra*, Part II (B); *see also* Motion Part III (B). Absent the requisite actual, physical harm, Plaintiff does not state a claim for relief. *Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (2008).

2. Plaintiff Fails to Plead That OptiMARK Was The Proximate Cause of Any Injury.

Plaintiff does not contest that she must adequately plead proximate cause. Opp. at 6-7. Plaintiff's contention appears to be that because the FAC includes the phrase "proximate cause," causation has been plausibly alleged. *Id.* Indeed, she points to paragraphs 182, 205, and 211 to illustrate that she used the term "proximate

cause." *Id.* But legal conclusions without adequate factual support are entitled to no assumption of truth. *Gen. Motors. Corp. v. New A.C. Chevrolet, Inc.*, 263 F.3d 296, 333 (3d Cir. 2001) (alteration in original; citation omitted). Here as above, the Opposition cites various passages in contention that the FAC sufficiently alleges proximate cause – but it does not. *See supra*. As such, the FAC fails to allege facts which, if assumed true, plausibly establish that the Guerbet Defendants' GBCA product is the proximate cause of any specific injury and should be dismissed.

3. Plaintiff Does Not Sufficiently Plead a Failure to Warn Claim Under the NJPLA.

The Opposition confirms that Plaintiff's failure to warn claim is deficient because it (1) fails to describe with specificity any duty owed by the Guerbet Defendants; (2) is preempted by federal law; and (3) fails to overcome the NJPLA presumption of adequacy for FDA-approved warnings.

First, the Opposition contends that Plaintiff's failure to warn claim sufficiently pled "what risks the Guerbet Defendants . . . had a duty to warn her about," Opp. at 7. But the Guerbet Defendants argued something different in the Motion: Plaintiff's claim fails because Plaintiff does not – as she must – allege that the Guerbet Defendants had at any time a duty to provide the warning(s) she asserts she should have been provided regarding any injury. Motion at 11-12. Despite claiming six exposures to OptiMARK over a nine-year period (2007-2016), the FAC does not link the alleged duty to warn to any defendant's awareness at any specific time of any plausible risk. *Id.* Plaintiffs' Opposition does not explain this deficiency. Moreover, the Opposition does not address the fact that to this day, there are no known injuries associated with the use of GBCAs in patients with normal renal function. *See supra*; *see also* Dkt. 56, Ex. B (December 2017 FDA statement: "Gadolinium retention has not been directly linked to adverse health effects in

patients with normal kidney function"). Accordingly, Plaintiff's failure to warn claim should be dismissed. Motion at 11-12.

Second, with regard to impossibility preemption, Plaintiff does not contest the basic preemption framework: (1) that a failure to warn claim requires a showing of sufficient "newly acquired evidence" to allow Plaintiff's desired warning; and (2) that a failure to warn claim is preempted when there is "clear evidence" that the FDA would have rejected Plaintiff's desired warning. *See* Opp. at 8;[3] Dkt. 85 at 5-9. The Opposition asserts that the FAC identifies sufficient "newly acquired evidence" and "clear evidence" that FDA would have rejected her desired warning is lacking here. *Id.* She is wrong on both fronts. *See* Motion 11-15.

With respect to "newly acquired evidence," the studies and evidence referenced in the FAC relate to gadolinium deposition. *See id.* And Plaintiff has conceded that retention of gadolinium is not the injury she complains of (and consequently cannot be the warning she demands). *See* Opp. at 7. Plaintiff fails to address the arguments raised in the Motion – 1) none of the cited studies demonstrate that clinical doses of GBCAs cause any injury in patients with normal renal function and 2) at most, these studies demonstrate that trace amounts of gadolinium can be retained in patients with normal renal function. Motion at 14. Plaintiff has failed to make out a cognizable failure to warn claim, because the FAC does not plead any "newly acquired information" sufficient to allow the warning she desires – that GBCAs cause injury in patients with normal renal function. *See* Motion 11-15.

[3] Plaintiff does not directly address the arguments raised by the Guerbet Defendants; rather the Opposition asserts that these arguments fail "for all the reasons set forth in the opposition to Mallinckrodt's preemption argument." Though similar in some respects, the preemption arguments raised in the Guerbet Defendants' Motion (Dkt. 77-1) and the Mallinckrodt Defendants' Memorandum In Support of Their Motion to Dismiss Plaintiff's First Amended Compliant (Dkt. 53) do not mirror one another in substance or authority. For this reason, the Guerbet Defendants respond here only to those arguments raised in the Mallinckrodt Opposition and arguments presented in its own Motion.

Next, Plaintiff concedes that her state law failure to warn claim is preempted by federal law if there is "clear evidence" that the FDA would have rejected her desired warning . *See* Dkt. 85 at 5-9. The Opposition modifies the clear evidence standard to require that the Guerbet Defendants demonstrate "that [they] went to FDA, asked to place such a warning on its OptiMARK label, and in turn, FDA took a legal action to stop that warning." *Id.* at 11 (citing *Merck Sharp & Dohme Corp v. Albrecht*, 139 S. Ct. 1668, 1672 (2019)). In truth, *Albrecht* did not mandate that labeling changes requested by the manufacturer are the only form of clear evidence that can establish impossibility preemption. *Id.* In *Albrecht*, "[t]he question of disapproval 'method' [wa]s not now before [the Court]." 139 S. Ct. at 1679.[4] Courts have agreed that other forms of evidence can establish preemption. *Cerveny v. Aventis, Inc.*, No. 17-4204, 2019 WL 3763411, at *3 (10th Cir. Aug. 9, 2019) (finding that "*Albrecht* did not dictate that only label changes sought by the manufacturer can lead to preemption" and recognizing other mechanism by which a defendant can demonstrate "clear evidence"); *see also, State v Purdue Pharma L.P.*, No. 08-2018-CV-01300, 2019 WL 3776653, at *2 (D. N.D. July 22, 2019) (noting that *Albrecht* "did not involve agency "actions" or "methods" similar to this case … [and] did not decide whether other agency actions … would be sufficient.").

What *Albrecht* does instruct is that "clear evidence" requires a showing that the FDA was informed of the "justification for the warning required by state law" and that the FDA would not allow such a warning. Motion 12-14. Here, Plaintiff does not dispute that the FDA was fully informed. *See* Dkt. 85 at 9; FAC at ¶ 46 ("FDA and the GBCA industry collaborated in an advisory committee meeting – the Medical Imaging Drugs Advisory Committee (MIDAC)"). "The focus of MIDAC's inquiry was the connection, if any, between the retention of GBCAs or gadolinium

[4] The issue decided by the *Albrecht* Court was that "the question of preemption is one for a judges to decide, not a jury." *Id.* at 1672.

in the body and various symptoms reported in patients with healthy kidneys." *Davis v. McKesson Corp.*, No. CV-18-1157-PHX-DGC, 2019 WL 3532179, at *5 (D. Ariz. Aug. 2, 2019). "After considering all of the evidence and hearing presentations from scholars, experts, and patient advocacy groups, MIDAC unanimously concluded that the medical and scientific evidence does not establish that GBCAs cause GDD." *Id.*

This *exact* conclusion is entrenched in the same 2018 label change by GBCA manufacturers that Plaintiff cites to support her claim. Dkt. 85 at 9-10; FAC ¶ 150. These undisputed facts constitute "clear evidence" that Plaintiff's suggested warnings related to *her injury* would not have been approved by the FDA.[5]

Finally, the Opposition concedes that under the NJPLA, FDA-approved warnings that accompany pharmaceutical products are presumed to be adequate as a matter of law. *Id.* at 8. Despite this concession, Plaintiff fails to explain how the FAC overcomes the presumption. *Id.* Rather, the Opposition claims that the only question at this stage is whether the "complaint adequately pleads the inadequacy of the warning." Opp. at 8. Plaintiff cites no legal authority to support this position, arguing only that she has met her own standard – but she has not. *Id.; see supra*. Plaintiff argues that the New Jersey Supreme Court reversed *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999) on grounds that the plaintiff in that case had overcome the presumption of adequacy. Opp. at 8. But this is incorrect. The New Jersey Supreme Court remanded *Perez* on learned intermediary doctrine grounds under the facts unique to that case. *See id.* at 1260. Indeed, the court in *Perez* ruled that "compliance with FDA standards should be dispositive" of failure to warn

[5] Plaintiff's underscoring of the 2016 update to the OptiMARK product label once again conflates gadolinium retention with injury. *See* Opp. at 8; Dkt. 85 at 9. That the OptiMARK label was updated in 2016 to include a discussion of gadolinium retention has no bearing on the "clear evidence" of FDA's rejection of *resultant injury* from gadolinium retention. Even still, Plaintiff admits that she continued to use the OptiMARK product even *after* its label was updated to include a discussion of gadolinium retention. *See* Motion at n. 9.

claims. *Id.* at 1259. Unlike *Perez*, Plaintiff fails to allege facts that can overcome this presumption.

4. Plaintiff Does Not Sufficiently Plead A Design Defect Claim Under the NJPLA.

Plaintiff's Opposition raises two arguments in defense of her design defect claim: 1) her design defect claim is not preempted under *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013); and 2) she has sufficiently pled a design defect claim under the NJPLA. Neither argument cures the deficiencies in the FAC.

First, Plaintiff asserts that *Bartlett* "does not stand for the proposition that a defective design claim over a brand name drug . . . is preempted by operation of an 'impossibility' conflict." Opp. at 9. This incomplete reading ignores the express findings of *Bartlett* (and other courts interpreting *Bartlett*): "Once a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Bartlett*, 570 U.S. at 477. Plaintiff fails to explain how (short of stop selling), under the prevailing regulatory framework, the Guerbet Defendants could have modified the chemical design of their product. Motion at 16-17.

Instead, through a tortured articulation of *Bartlett*, she reduces its holding to nothing more than an unchanging application of the Supreme Court's previous holding in *PLIVA v. Mensing*, 564 U.S. 604, 614-15 (2011). Opp. at 9-10 (arguing that the design defect claim at issue in *Bartlett* "boiled down to a failure to warn claim" and therefore was actually preempted under *Mensing*). Plaintiff cites no legal authority in support of this conclusion.

Moreover, Plaintiff is incorrect to suggest that the design defect impossibility preemption found in *Bartlett* may only be invoked by a generic drug manufacturer. Opp. at 9-10. For example, federal regulations prohibit a brand drug manufacturer

from altering the formulation of their products following FDA approval – a fact the *Bartlett* Court expressly acknowledges. *See* 21 C.F.R. § 314.70(b)(2)(i); *Bartlett*, 570 U.S. at 477 ("[o]nce a drug—whether generic or *brand-name*—is approved, the manufacturer is prohibited from making any major changes to the qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application") (emphasis added). Courts interpreting *Bartlett* have agreed and found that impossibility preemption is applicable to both generic and brand name drug products. *Yates v. Ortho-McNeil-Janssen Pharm., Inc*., 808 F.3d 281, 298 (6th Cir. 2015) (federal law prohibits defendants from altering their product once approved).

Additionally, in trying to distinguish her design defect and failure to warn claims, Plaintiff argues that the "safer alternative design and structure already exists and has long been FDA-approved" (i.e., a macrocyclic GBCA, as opposed to a linear GBCA). Opp. at 10. This argument would mandate the OptiMARKproduct be altered such that it becomes a new drug product. For the reasons stated above, such a claim is preempted. This contention amounts to an argument that the OptiMARK product (in its existence as an FDA-approved linear GBCA), either: 1) should never have been sold or 2) should cease to be sold. Both of these arguments fail. *Bartlett*, 570 U.S. at 489 (explaining such a "stop-selling rationale" cannot overcome preemption); *Yates* (rejecting a "never-start-selling" rational for the same reasons as *Bartlett*); *see also*, Motion 16-17. The Opposition offers no rebuttal to this argument. Opp. at 9-10.

Second, irrespective of preemption, Plaintiff does not dispute that in order to make out a design defect claim under the NJPLA, "[she] must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570 (1998). She maintains that the macrocyclic

structure sufficiently states a design defect claim under either theory. But this does not – as it must – "prove that a practical and feasible alternative design existed that would have reduced or prevented [her] harm." *Mays v. Gen. Binding Corp.*, No. 11-5836, 2013 WL 1986393, at *6 (D. N.J. May 10, 2013). In fact, Plaintiff alleges that purported studies "acknowledging *gadolinium deposition*" establish the existence of the purported alternative design. But gadolinium deposition is not the injury Plaintiff complains of, nor a cognizable injury at all. *See supra*.

C. PLAINTIFF DOES NOT SUFFICIENTLY PLEAD A CLAIM FOR BREACH OF EXPRESS WARRANTY.

As set forth in the Motion, Plaintiff's FAC fails to allege any statement by the Guerbet Defendants to Plaintiff on which a warranty claim could be premised. The Opposition does not dispute that in order to prevail on her breach of express warranty claim under New Jersey law, Plaintiff must show: "(1) that [the] [d]efendant made an affirmation, promise, or description about the product; (2) that this affirmation, promise or description became part of the *basis of the bargain* for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691 at 706 (D. N.J. 2011); *see* N.J.S.A. § 12A:2—313. Moreover, Plaintiff does not dispute that she must "identify the actual *language* or source of th[e] warranty, or specify when the warranty was in effect" and must further "provide the *language* of any advertisements, promotional or marketing materials, point[-]of-sale displays, or product specifications" that contained the alleged warranty. *Fishman v. Gen. Elec. Co.*, Civ. No. 2:12-00585, 2013 WL 1845615 at *5 (D. N.J. Apr. 30, 2013) (citing *Arlandson*, 792 F. Supp. 2d 691 at 707) (emphasis added); *see also* Motion 18-19.

Plaintiff contends that the FAC adequately identifies the express statements because:

> [she] pleads that each Defendant expressly warranted, by way of affirmation, promise, and/or description in their product labeling, marketing, advertising, promotion, and educational efforts, that: (1) linear GBCAs are generally safe for use; (2) linear GBCAs are not any less safe or stable than macrocyclic GBCAs; (3) GBCAs pose a risk of NSF only to patients with kidney conditions; (4) GBCAs are contraindicated only in patients with chronic, severe kidney disease, acute kidney injury, or a history of severe hypersensitivity; and (5) any retention of gadolinium in non-kidney patients is harmless.

Opp. at 10. This concedes that Plaintiff is unable to identify any specific statement made to her by the Guerbet Defendants. Likewise, Plaintiff has not identified a specific statement that formed any bargain. The vague legal conclusions recited in the FAC are not enough. *Id*.; FAC ¶209. Plaintiff's claim for breach of express warranty should be dismissed. *Parker v. Howmedica Osteonics Corp.*, Civ. No. 07-2400, 2008 WL 141628, at *6 (D. N.J. Jan. 14, 2008); Motion 18-19.

D. PLAINTIFF'S CLAIM FOR PUNITIVE DAMAGES IS UNAVAILABLE UNDER NEW JERSEY LAW AND SHOULD BE DISMISSED.

The Opposition does not contest the general rule that under New Jersey law, punitive damages are typically unavailable in personal injury cases involving prescription drugs. *See* Motion 19-21. The single statutory exception to this general rule has consistently been found to be preempted by courts in New Jersey and within this District. *Id.* at n.10 (citing cases).

Although the Opposition argues that Plaintiff's punitive damages claims are not preempted and therefore should not be dismissed, Plaintiff fails to cite a single New Jersey legal authority in support of her position. *See* Opp. at 11-12.[6] *Id.* For reasons articulated in the Motion, Plaintiff's request for punitive damages should be dismissed. Motion 19-21.

[6] The Opposition relies exclusively on a New York District Court's interpretation of New York state law.

III. CONCLUSION

For the aforementioned reasons and the reasons set forth in the Motion, Defendants Guerbet LLC and Liebel-Flarsheim Company, LLC respectfully request that this Court dismiss Plaintiff's First Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6).

Dated: October 15, 2019 Respectfully submitted,

KENDALL LAW PC
Jamie L. Kendall (NJ ID No. 016492004)
Brad M. Welsh (NJ ID No. 076132013)
Alexandra H. Schulz (NJ ID No. 157612015)
308 E. Lancaster Avenue, Suite 315
Wynnewood, Pennsylvania 19096
jkendall@tkfirm.com
bwelsh@tkfirm.com
aschulz@tkfirm.com
Facsimile: 1.484.841.2067
Telephone: 1.484.414.4093

/s/ *Brian W. Shaffer*
MORGAN LEWIS & BOCKIUS LLP
(A Pennsylvania Limited Liability Partnership)
Brian W. Shaffer (NJ ID No. 025651996)
1701 Market Street
Philadelphia, Pennsylvania 19103-2921
brian.shaffer@morganlewis.com
Facsimile: 1.215.963.5001
Telephone: 1.215.963.5000

Attorneys for Defendants,
Guerbet LLC and Liebel-Flarsheim Company, LLC